PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

,
)
)
)
)
)
)
))

AMENDED APPEAL BRIEF

Mail Stop Appeal Brief- Patents Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

This is an amended Appeal Brief in response to the Notice of Non-Compliant Appeal Brief. This amended Appeal Brief discusses the status of canceled claim 30 (see pages 3 and 23). Applicants note that an Examiner's Answer has already been received. This is NOT a reply brief in response to the Examiner's Answer. Applicants reserve the right to file a reply brief.

The above-captioned patent application is respectfully submitted to the Honorable Board of Patent Appeals and Interferences after final rejection by Examiner Sang Yeop Paik, Group Art Unit 3742, refusing allowance of the claims as presented and amended in the above-captioned patent application. A copy of the claims in issue is included herewith in the Appendix.

The Appeal Brief is in furtherance of the Notice of Appeal filed in this case on May 22, 2006.

The Commissioner is authorized to charge any fee required for this paper to Deposit Account No. 20-1495.

This brief contains the following items under the following headings and in the order set forth below (37 CFR 41.37(c)):

- I. Real Party in Interest;
- II. Related Appeals and Interferences;
- III. Status of Claims;
- IV. Status of Amendments;
- V. Summary of Claimed Subject Matter;
- VI. Grounds of Rejection to be Reviewed on Appeal;
- VII. Argument;
- VIII. Claims Appendix;
- IX. Evidence Appendix;
- X. Related Proceedings Appendix; and

The final page of this brief bears the conclusion and the attorney's signature.

I. REAL PARTY IN INTEREST (37 CFR 41.37(c)(1)(i))

The real party in interest is the Assignee of the present patent application, Fisher & Paykel Healthcare Limited, a corporation organized and existing under the laws of New Zealand, having its principal place of business at 15 Maurice Paykel Place, East Tamaki, Auckland, New Zealand.

II. RELATED APPEALS AND INTERFERENCES (37 CFR 41.37(c)(1)(ii))

There are no other prior or pending appeals, interferences or judicial proceedings known to the Appellant, Appellant's legal representative, or Assignee which may be related to, directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF THE CLAIMS (37 CFR 41.37(c)(1)(iii))

Claims 1-14, 16-29, 31 and 32 stand finally rejected and are on appeal.

Claim 15 is objected to, based upon an alleged claim informality, and is not on appeal.

Applicants submitted an amendment on December 5, 2005 in response to the Office Action of August 8, 2005 amending claim 15 to remove the claim informality. Therefore, claim 15 should be allowable.

Claim 30 has been canceled.

IV. STATUS OF AMENDMENTS (37 CFR 41.37(c)(1)(iv))

No amendments after the final rejection were submitted.

V. SUMMARY OF CLAIMED SUBJECT MATTER (37 CFR 41.37(c)(1)(v))

Each of claims 1, 13, 17 and 32 determine a parameter related to the flow rate of gas through a breathing assistance apparatus (1), and use this parameter to control the power supplied to a humidifier (2, 3). Claims 1, 13 and 32 claim an apparatus, and claim 17 claims a method. Claim 32 is written in means plus function form.

Independent claims 1 and 13 and claim 17 claim an apparatus and method, respectively. Claims 1 and 13 claim a breathing assistance apparatus (1) adapted to deliver humidified gases at a desired level of humidity or at a desired temperature to a patient using open loop control. Claim 17 claims a method of delivering humidified gas at a desired level of humidity or at a desired temperature to a patient using open loop control. In each claim, a parameter relating to the flow rate of the gases through the apparatus is determined (page 7, lines 21-23; page 8, lines 19-20; step 136 in Fig. 4; page 11, lines 7-10; page 12, lines 3-22; page 12, lines 25-27); based on at least the parameter, the required electrical power input to the humidifier (2, 3) to deliver the gases to the patient (at end 7) at a level of humidity or at a temperature substantially similar to the desired level of humidity or the desired temperature is determined (page 7, lines 23-25; page 8, line 21 through page 9, line 2; step 138 in Fig. 4); and a level of power substantially similar to the determined power input to the humidifier is supplied as the input power (108) to the humidifier (page 9, lines 3-19). Claim 1 specifically recites a controller or processor (100; Fig. 3) for effecting these steps.

Independent claim 13 additionally claims a conduit (6) for conveying the humidified gases from the humidifier to the patient (at end 7). In addition, as discussed on page 9, line 21 through page 10, line 27 and as shown in Fig. 4, the controller or processor (100) continuously

monitors the parameter and when a change in the parameter is greater than a first threshold, the controller or processor reverts to determining based on at least the parameter the required electrical power input to the humidifier to deliver the gases to the patient at a level of humidity or at a temperature substantially similar to the desired level of humidity or the desired temperature, and when a change in the parameter is greater than a second threshold the controller or processor reverts to determining a parameter relating to the flow rate of the gases through the apparatus. If the change in the parameter indicates a decrease in flow a relatively short delay is caused before the controller or processor reverts to determining based on at least the parameter the required electrical power input to the humidifier to deliver the gases to the patient at a level of humidity or at a temperature substantially similar to the desired level of humidity or the desired temperature and if the change indicates an increase in flow a relatively long delay is caused before the controller or processor reverts to determining based on at least the parameter the required electrical power input to the humidifier to deliver the gases to the patient at a level of humidity or at a temperature substantially similar to the desired level of humidity or the desired temperature.

Independent claim 32 claims a breathing assistance apparatus (1) adapted to deliver humidified gas at a desired level of humidity or at a desired temperature to a patient using open loop control. The breathing assistance apparatus (1) includes humidifier means (2, 3, 8, 20; page 6, line 24 through page 7, line 2; page 7, lines 3 and 8-10) having an electrical input power (108) and capable of humidifying the gas up to a level of humidity prior to delivery to the patient (at end 7), the level of humidity depending on the input power (108) to the humidifier, means for determining a parameter relating to the flow rate of the gas (page 7, lines 21-23; page 8, lines 19-20; step 136 in Fig. 4; page 11, lines 7-10; page 12, lines 3-22; page 12, lines 25-27) through the

apparatus; means for determining based on at least the parameter the required electrical power input to the humidifier to deliver the gas to the patient at a level of humidity or at a temperature substantially similar to the desired level of humidity or the desired temperature (page 7, lines 23-25; page 8, line 21 through page 9, line 2; step 138 in Fig. 4); means for supplying as the input power to the humidifier a level of power substantially similar to the determined power input (108) to the humidifier (page 9, lines 3-19).

Independent claim 16 claims a breathing assistance apparatus (1) adapted to deliver humidified gases at a desired level of humidity or at a desired temperature to a patient. The breathing assistance apparatus includes a humidifier (2, 3) having an electrical input power (108) capable of humidifying the gases up to a level of humidity prior to delivery to the patient (at end 7), the level of humidity depending on the input power to the humidifier, a conduit (6) for conveying the humidified gases from the humidifier to the patient, and a conduit heater (10) having an electrical input power (114), and being associated with the conduit wherein the gases flowing through the conduit are heated either directly or indirectly by the conduit heater. The level of heating depends on the input power to the conduit heater. A controller or processor (100) supplies the input power to the humidifier and the conduit heater, and provides a control output indicative of the conduit heater being correctly connected to the controller or processor and capable of operating in according within predefined limits (page 13, lines 1-7). A connector (200, Fig. 1) is provided to electrically connect the controller or processor and the conduit heater (page 12, line 31 through page 13, line 1) and including an indicator (202, Fig. 1) in use connected to the control output, wherein when the conduit heater is correctly connected to the controller or processor and capable of operating in according within predefined limits the

controller or processor energise the indicator.

Independent claim 31 claims a method of connecting a conduit heater (10) within a conduit (6) to a humidifier (2, 3) including the steps of providing an electrical connection (200, Fig. 1; page 12, line 31 through page 13, line 1) between the conduit heater and the humidifier; and indicating whether conduit is being correctly connected and capable of operating in according within predefined limits (page 13, lines 1-7).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL (37 CFR 41.37(c)(1)(vi))

- 1. Whether claims 1, 16, 17, 31 and 32 are patentable over the Examiner's rejection under 35 U.S.C. §102(b) as allegedly being anticipated by United States Patent No. 5,558,084 to Daniell et al.
- 2. Whether claims 3-7, 13, 14, 19-23 and 29 are patentable over the Examiner's rejection under 35 U.S.C. §103 as allegedly being unpatentable over Daniell et al.

VII. ARGUMENT (37 CFR 41.37(c)(1)(vii))

1. Rejection under 35 U.S.C. §102(b) over U.S. Patent No. 5,558,084 to Daniell et al.

A. Claims 1, 17 and 32

Each of claims 1, 17 and 32 determine a parameter related to the flow rate of gas through the apparatus, and use this parameter to control the power supplied to a humidifier. Claim 1 specifies "(a) determine a parameter relating to the flow rate of said gases through said apparatus; (b) determine based on at least said parameter the required electrical power input to said humidifier to deliver said gases to said patient at a level of humidity or at a temperature substantially similar to said desired level of humidity or said desired temperature; and (c) supply as said input power to said humidifier a level of power substantially similar to said determined power input to said humidifier." Claim 17 specifies "(a) determining a parameter relating to the flow rate of said gas through said humidifier; (b) determining based on at least said parameter the required electrical power to said humidifier to deliver said gas to said patient at a level of humidity or at a temperature substantially similar to said desired level of humidity or said desired temperature; and (c) supplying a level of power to said humidifier substantially similar to said determined power." Claim 32 specifies "means for determining a parameter relating to the flow rate of said gas through said apparatus; means for determining based on at least said parameter the required electrical power input to said humidifier to deliver said gas to said patient at a level of humidity or at a temperature substantially similar to said desired level of humidity or said desired temperature; means for supplying as said input power to said humidifier a level of power substantially similar to said determined power input to said humidifier."

Applicants submit that the limitation "a parameter relating to the flow rate" in each of claims 1, 17 and 32 means a parameter from which the flow rate can be determined or estimated without the need for any further measurements.

The Examiner argues that the temperature of the humidified gas, as sensed by a chamber sensor 8 in Daniell et al., is a parameter relating to the flow rate of gas through the apparatus. However, the temperature of the humidified gas is not related to the flow rate of the gas. Knowledge of the temperature of the gas provides no information about its flow rate. As admitted by the Examiner, it is possible to have high and low flow rate at high and low temperatures.

The Examiner's argues that higher temperature gas in a chamber leads to higher pressure in a chamber and so a higher flow rate out of the chamber. However, this argument is doubly flawed. It assumes that a humidifying chamber contains the same number of moles of gas at all times. That is not the case. Accordingly, higher temperature does not necessarily equal higher pressure in a humidifying chamber. The argument also assumes that there is a constant pressure in the outlet from the humidifying chamber and so higher pressure in the chamber means a higher pressure difference between camber and outlet. In fact, there is not necessarily a pressure difference at all between the inside of a humidifying chamber and the outlet from the humidifying chamber. Accordingly, a higher pressure in the humidifying chamber does not mean higher flow rate out of the chamber.

In any case, the dominant factors affecting the flow rate in a typical breathing assistance apparatus are a fan which is used for blowing air, oxygen or anaesthetic through the apparatus and the breathing of the patient who receives the humidified air. It is not a closed, static system.

Therefore, Applicants submit that Daniell et al. does not anticipate claims 1, 17 and 32.

B. Claims 16 and 31

Claims 16 and 31 relate to providing an output indicative of a correct connection between a conduit heater and a controller. Specifically, apparatus claim 16 specifies "a controller or processor which . . . provides a control output indicative of said conduit heater being correctly connected to said controller or processor and capable of operating in according within predefined limits" and method claim 31 specifies "indicating whether conduit is being correctly connected and capable of operating in according within predefined limits".

Daniell et al. only discloses an alarm which sounds when something is incorrectly connected, not correctly connected. Daniell et al. also discloses a display, but there is no disclosure that this display indicates when the conduit heater is correctly connected to a controller. The only information that is mentioned is a display of ambient temperature or a difference between the ambient temperature and the temperature of the gas in the humidifier.

Therefore, Applicants submit that Daniell et al. does not anticipate claims 16 and 31.

2. Rejection under 35 U.S.C. §103 over U.S. Patent No. 5,558,084 to Daniell et al.

A. <u>Claim 13</u>

Like claims 1, 17 and 32 discussed hereinabove, claim 13 determines a parameter related to the flow rate of gas through the apparatus, and uses this parameter to control the power supplied to a humidifier. Specifically, claim 13 specifies "(a) determine a parameter relating to the flow rate of said gases through said apparatus; (b) determine based on at least said parameter

the required electrical power input to said humidifier to deliver said gases to said patient at a level of humidity or at a temperature substantially similar to said desired level of humidity or said desired temperature; (c) supply as said input power to said humidifier a level of power substantially similar to said determined power input to said humidifier".

Applicants submit that the limitation "a parameter relating to the flow rate" in claim 13 means a parameter from which the flow rate can be determined or estimated without the need for any further measurements.

The Examiner argues that the temperature of the humidified gas, as sensed by a chamber sensor 8 in Daniell et al., is a parameter relating to the flow rate of gas through the apparatus. However, the temperature of the humidified gas is not related to the flow rate of the gas. Knowledge of the temperature of the gas provides no information about its flow rate. As admitted by the Examiner, it is possible to have high and low flow rate at high and low temperatures.

The Examiner's argues that higher temperature gas in a chamber leads to higher pressure in a chamber and so a higher flow rate out of the chamber. However, this argument is doubly flawed. It assumes that a humidifying chamber contains the same number of moles of gas at all times. That is not the case. Accordingly, higher temperature does not necessarily equal higher pressure in a humidifying chamber. The argument also assumes that there is a constant pressure in the outlet from the humidifying chamber and so higher pressure in the chamber means a higher pressure difference between camber and outlet. In fact, there is not necessarily a pressure difference at all between the inside of a humidifying chamber and the outlet from the humidifying chamber. Accordingly, a higher pressure in the humidifying chamber does not mean

higher flow rate out of the chamber.

In any case, the dominant factors affecting the flow rate in a typical breathing assistance apparatus are a fan which is used for blowing air, oxygen or anaesthetic through the apparatus and the breathing of the patient who receives the humidified air. It is not a closed, static system.

Therefore, Applicants submit that Daniell et al. does not render obvious claim 13.

B. Claims 3-7, 13, 14, 19-23 and 29

Claims 3-7, 13, 14, 19-23 and 29 specify a control strategy which is undertaken to control the breathing assistance apparatus. As an example, independent claim 13 specifies:

a controller or processor including stored instructions to:

- (a) determine a parameter relating to the flow rate of said gases through said apparatus;
- (b) determine based on at least said parameter the required electrical power input to said humidifier to deliver said gases to said patient at a level of humidity or at a temperature substantially similar to said desired level of humidity or said desired temperature;
- (c) supply as said input power to said humidifier a level of power substantially similar to said determined power input to said humidifier;
- (d) continuously monitor said parameter and when a change in said parameter is greater than a first threshold said controller or processor reverts to said instruction (b) and when a change in said parameter is greater than a second threshold said controller or processor reverts to instruction (a).

wherein if said change in said parameter indicates a decrease in flow a relatively short delay is caused before said controller or processor reverts to said instruction (b) and if said change indicates an increase in flow a relatively long delay is caused before said controller or processor reverts to said instruction (b).

The Examiner has stated that while Daniell et al. does not explicitly disclose the claimed sequence of steps, it would have been obvious to provide the controller with means to perform such steps.

Applicants disagree with the Examiner and Applicants have repeatedly requested that the Examiner to support this assertion, as there is nothing in Daniell et al. which would suggest the particular control strategy that is cover by these claims. The Examiner appears to be saying that because the prior art shows a system in which heaters are controlled in response to a measurement of temperature, it would be obvious to control heaters in response to measurement of any system parameters and according to any kind of control strategy. Applicants submit that without a disclosure or suggestion in Daniell et al. of same, that this cannot stand under 35 U.S.C. §103.

Therefore, because Daniell et al. does not disclose or suggest the limitations of these claims, Applicants submit that Daniell et al. does not render obvious claims 3-7, 13, 14, 19-23 and 29.

VIII. CLAIMS APPENDIX (37 CFR 41.37(c)(1)(viii))

1. A breathing assistance apparatus adapted to deliver humidified gases at a desired level of humidity or at a desired temperature to a patient using open loop control comprising:

a humidifier having an electrical input power and capable of humidifying said gases up to a level of humidity prior to delivery to said patient, said level of humidity depending on said input power to said humidifier, and

a controller or processor configured or programmed to:

- (a) determine a parameter relating to the flow rate of said gases through said apparatus;
- (b) determine based on at least said parameter the required electrical power input to said humidifier to deliver said gases to said patient at a level of humidity or at a temperature substantially similar to said desired level of humidity or said desired temperature; and
- (c) supply as said input power to said humidifier a level of power substantially similar to said determined power input to said humidifier.
- 2. A breathing assistance apparatus as claimed in claim 1 further comprising: a conduit for conveying said humidified gases from said humidifier to said patient a conduit heater having an electrical input power, and being associated with said conduit wherein the gases flowing through said conduit are heated either directly or indirectly by said conduit heater whereby the level of heating depending on said input power to said conduit heater; and

an ambient temperature sensor providing an indication of the exterior temperature or said

controller or processor including a stored assumption used as an indication of the exterior temperature;

wherein instruction (b) further comprises determining based on at least said indication of the exterior temperature the required power input to said conduit heater to deliver said gases to said patient at a level of humidity or at a temperature substantially similar to said desired level of humidity or said desired temperature;

and said instruction (c) further comprises supplying as said input power to said conduit heater a level of power substantially similar to said determined power input to said conduit heater.

- 3. A breathing assistance apparatus as claimed in claim 2 wherein said humidifier comprises a humidification chamber adapted to receive a volume of water and a water heater to heat said water to produce water vapour within said chamber in use, said gases passing through said water vapour in said chamber thereby being humidified, said instruction (a) further comprising:
 - i) energise said water heater to heat said water towards a first condition,
- ii) determine a variable indicative of a property of said water heater and continually monitoring said variable, until said variable or said parameter indicates that said water has substantially reached said first condition,
- iii) determine said parameter based on at least said variable and said indication of the external temperature.

- 4. A breathing assistance apparatus as claimed in claim 3 wherein the determination of said power to said humidifier in said instruction (b) is also based on said indication of the external temperature.
- 5. A breathing assistance apparatus as claimed in claim 3 wherein said controller or processor stores a further instruction:
- (d) continuously monitor said parameter or said variable, and when a change in said parameter or said variable is greater than a first threshold said controller or processor reverts to said instruction (b) and when a change in said parameter or said variable is greater than a second threshold said controller or processor reverts to instruction (a).
- 6. A breathing assistance apparatus as claimed in claim 5 wherein said second threshold is based on the rate of change of said parameter with respect to time, and wherein when said rate of change goes over said second threshold said controller or processor reverts to said instruction (a).
- 7. A breathing assistance apparatus as claimed in any one of claims 3 to 6 further comprising:

a chamber sensor means providing an indication of the temperature of said water heater and providing an indication of the electrical power drawn by said water heater,

wherein said variable is indicative of said indication of the temperature of said water heater or said indication of the power drawn by said water heater.

- 8. A breathing assistance apparatus as claimed in claims 1 or 2 further comprising a gas supply adapted to supply gases to said humidifier at a required pressure and resulting flow rate.
- 9. A breathing assistance apparatus as claimed in claim 8 wherein said gas supply provides an output signal representative of the level of electrical input to said gas supply, said signal being supplied to said controller or processor and from which the flow rate of said humidified gases is determined.
- 10. A breathing assistance apparatus as claimed in claim 8 wherein said gas supply comprises a fan driven by a variable speed electric motor.
- 11. A breathing assistance apparatus as claimed in claim 10 wherein said estimate of the flow rate of said humidified gases is based on the current drawn by said variable speed motor.
- 12. A breathing assistance apparatus as claimed in claims 1 or 2 further comprising a gases flow rate sensor from which said estimate of the flow rate of said humidified gases is determined directly.

13. A breathing assistance apparatus adapted to deliver humidified gases at a desired level of humidity or at a desired temperature to a patient comprising:

a humidifier having an electrical input power and capable of humidifying said gases up to a level of humidity prior to delivery to said patient, said level of humidity depending on said input power to said humidifier,

a conduit for conveying said humidified gases from said humidifier to said patient, and a controller or processor including stored instructions to:

- (a) determine a parameter relating to the flow rate of said gases through said apparatus;
- (b) determine based on at least said parameter the required electrical power input to said humidifier to deliver said gases to said patient at a level of humidity or at a temperature substantially similar to said desired level of humidity or said desired temperature;
- (c) supply as said input power to said humidifier a level of power substantially similar to said determined power input to said humidifier;
- (d) continuously monitor said parameter and when a change in said parameter is greater than a first threshold said controller or processor reverts to said instruction (b) and when a change in said parameter is greater than a second threshold said controller or processor reverts to instruction (a).

wherein if said change in said parameter indicates a decrease in flow a relatively short delay is caused before said controller or processor reverts to said instruction (b) and if said change indicates an increase in flow a relatively long delay is caused before said controller or processor reverts to said instruction (b).

14. A breathing assistance apparatus as claimed in claim 13 further comprising:

a chamber sensor means providing an indication of the temperature of said water heater and providing an indication of the electrical power drawn by said water heater,

wherein said variable is indicative of said indication of the temperature of said water heater or said indication of the power drawn by said water heater.

16. A breathing assistance apparatus adapted to deliver humidified gases at a desired level of humidity or at a desired temperature to a patient comprising:

a humidifier having an electrical input power capable of humidifying said gases up to a level of humidity prior to delivery to said patient, said level of humidity depending on said input power to said humidifier,

a conduit for conveying said humidified gases from said humidifier to said patient, and a conduit heater having an electrical input power, and being associated with said conduit wherein the gases flowing through said conduit are heated either directly or indirectly by said conduit heater wherein the level of heating depends on said input power to said conduit heater;

a controller or processor which supplies said input power to said humidifier and said conduit heater, and provides a control output indicative of said conduit heater being correctly connected to said controller or processor and capable of operating in according within predefined limits; and

a connector to electrically connect said controller or processor and said conduit heater and including an indicator in use connected to said control output, wherein when said conduit heater is correctly connected to said controller or processor and capable of operating in according within

predefined limits said controller or processor energise said indicator.

- 17. A method of delivering humidified gas at a desired level of humidity or at a desired temperature to a patient using an open loop controlled humidifier comprising the steps of:
- (a) determining a parameter relating to the flow rate of said gas through said humidifier;
- (b) determining based on at least said parameter the required electrical power to said humidifier to deliver said gas to said patient at a level of humidity or at a temperature substantially similar to said desired level of humidity or said desired temperature; and
- (c) supplying a level of power to said humidifier substantially similar to said determined power.
- 18. A method as claimed in claim 17 further comprising the steps: conveying said humidified gas to a patient; heating the conveyed gas either directly or indirectly using a conduit heater; and sensing or making an assumption of the exterior temperature;

wherein said step (b) further comprises determining based on at least said indication of the exterior temperature the required power input to said conduit heater to deliver said gas to said patient at a level of humidity or at a temperature substantially similar to said desired level of humidity or said desired temperature;

and wherein said step (c) further comprises supplying as said input power to said conduit heater a level of power substantially similar to said determined power input to said conduit

heater.

- 19. A method as claimed in claim 18 wherein said humidifier comprises a humidification chamber adapted to receive a volume of water and water heater to heat said water to produce water vapour within said chamber in use, said gas passing through said water vapour in said chamber thereby being humidified, said step (a) further comprising:
 - i) energising said water heater to heat said water towards a first condition,
- ii) continuously monitoring or a variable indicative of a property of said water heater, until said variable or indicates that said water has substantially reached said first condition,
- iii) determining a parameter based on at least said variable and said indication of the exterior temperature.
- 20. A method as claimed in claim 19 wherein the determination of said power to said humidifier in said instruction (b) is also based on said indication of the external temperature.
- 21. A method as claimed in claim 20 further comprising the step:
- (d) continuously monitoring said parameter or said variable, and when a change in said parameter or said variable is greater than a first threshold revert to step (b) and when a change in said parameter or said variable is greater than a second threshold revert to step (a).

- 22. A method as claimed in claim 21 further comprising the step of when said rate of change or said change in said parameter indicates a decrease in flow pausing for a first delay before said controller or processor reverts to step (a) and when said rate of change or said change indicates an increase in flow pausing for a second delay before reverting to step (a), said second delay being longer than said first delay.
- 23. A method as claimed in claim 22 wherein said second threshold is based on the rate of change of said parameter or said variable with respect to time, and further comprising the step of when said rate of change goes over said second threshold reverting to step (a).
- 24. A method as claimed in claim 17 further comprising the step of supplying gas to said humidifier at a required pressure and resulting flow rate.
- 25. A method as claimed in claim 24 further comprising the step of determining the level of electrical power required to supply said gas at a required pressure and resulting flow rate, from which the flow rate of said humidified gas is determined.
- 26. A method as claimed in claims 25 wherein said gas is supplied by a fan driven by a variable speed electric motor.
- 27. A method as claimed in claim 26 wherein said estimate of the flow rate of said humidified gas is based on the current drawn by said variable speed motor.

- 28. A method as claimed in claim 26 wherein said estimate of the flow rate of said humidified gas is determined directly from a gas flow rate sensor.
- 29. A method as claimed in claim 19 further comprising the step of:

sensing the temperature of said water heater and providing an indication of the electrical power drawn by said water heater,

wherein said variable is indicative of the temperature of said water heater or said indication of the power drawn by said water heater.

- 30. (Canceled)
- 31. A method of connecting a conduit heater within a conduit to a humidifier comprising the steps of:

providing an electrical connection between said conduit heater and said humidifier; and indicating whether conduit is being correctly connected and capable of operating in according within predefined limits.

32. A breathing assistance apparatus adapted to deliver humidified gas at a desired level of humidity or at a desired temperature to a patient using open loop control comprising:

humidifier means having an electrical input power and capable of humidifying said gas up to a level of humidity prior to delivery to said patient, said level of humidity depending on said input power to said humidifier,

means for determining a parameter relating to the flow rate of said gas through said apparatus;

means for determining based on at least said parameter the required electrical power input to said humidifier to deliver said gas to said patient at a level of humidity or at a temperature substantially similar to said desired level of humidity or said desired temperature;

means for supplying as said input power to said humidifier a level of power substantially similar to said determined power input to said humidifier.

IX. EVIDENCE APPENDIX (37 CFR 41.37(c)(1)(ix))

There was no evidence submitted pursuant to 37 C.F.R. §§ 1.130, 1.131 or 1.132 or any other evidence entered by the Examiner and relied upon by appellant in the appeal.

X. RELATED PROCEEDINGS APPENDIX (37 CFR 41.37(c)(1)(x))

There have been no decisions rendered by a court or the Board in any proceeding identified pursuant to paragraph 37 C.F.R. §41.37(c)(1).

Therefore, Appellant respectfully requests that the Board:

- 1. Reverse the final rejection of claims 1-14, 16-29, 31 and 32 in the present application;
- 2. Direct the Examiner to withdraw the rejection under 35 U.S.C. §102(b); and
- 3. Direct the Examiner to withdraw the rejection under 35 U.S.C. §103; and
- 4. Direct the Examiner to proceed with issuance of the present application.

This Appeal Brief is respectfully submitted by:

Attorneys for Applicant/Appellant

Date: 2006

By: Raiford A. Blackstone, Jr., Reg. No. 25,156

Linda L. Palomar, Reg. No. 37,903

TREXLER, BUSHNELL, GIANGIORGI, BLACKSTONE & MARR, LTD.

105 West Adams Street

Suite 3600

Chicago, Illinois 60603-6299

(312) 704-1890

9D8661.WPD